IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TRACEY SILER AND CHRIS SILER,

Plaintiffs,

vs.

AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. d/b/a ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SAINT THOMAS OUTPATIENT NEUROSURGICAL CENTER, LLC, HOWELL ALLEN CLINIC A PROFESSIONAL CORPORATION,

Defendants.

MDL No. 1:13-md-2419-FDS

NO. _____
JURY DEMAND

COMPLAINT

Plaintiff, TRACEY SILER and her spouse CHRIS SILER sue the Defendants and allege:

INTRODUCTION

1. This lawsuit arises as a result of an outbreak of fungal meningitis that has affected people in at many states. Many hundreds have been diagnosed with meningitis and/or fungal infections.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically methylprednisolone acetate (sometimes referred to as

"MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff and for many others who have suffered serious injuries.

4. During the period June through August 2012, Saint Thomas Outpatient Neurosurgical Center, LLC, ("Saint Thomas Neurosurgical") purchased thousands of vials of MPA from NECC and then sold and administered the MPA to patients, including Plaintiff.

5. During August of 2012, Plaintiff received lumbar epidural steroid injections ("ESI") at Saint Thomas Neurosurgical and/or its affiliated entity. During those procedures a medical doctor injected MPA into Plaintiff's body.

6. One or more of Plaintiff's epidural steroid injections came from contaminated lots of MPA that were purchased from NECC. The contaminated lots were subsequently recalled by NECC.

7. Plaintiff's injections of MPA caused meningitis.

PARTIES

8. Plaintiffs are citizens and residents of Tennessee.

9. Defendant Ameridose, LLC, ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts, 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent, is Gregory Conigliaro.

10. Defendant Medical Sales Management, Inc., ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts

with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.

11. Defendant Medical Sales Management SW, Inc., ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director. MSMSW's registered agent is Gregory Conigliaro.

12. Defendant GDC Properties Management, LLC, ("GDC") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts, 01702. GDC's manager and registered agent is Gregory Conigliaro.

13. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

14. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093, and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), which is a Massachusetts

corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden is the Treasurer and Director of MSM and MSMSW.

15. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts, 01701, and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts, 02093, and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.

17. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026, and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and a Director of MSM and MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

18. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts, 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

19. Defendant Glenn A. Chin ("Glenn Chin") is an individual residing at 173 Mechanic Street, Canton, Massachusetts, 02021, and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glen Chin, upon information and belief, compounded drugs at NECC.

20. Defendant Saint Thomas Outpatient Neurosurgical Center, LLC, ("Saint Thomas Neurosurgical") is a Tennessee for-profit limited liability company organized and domesticated under the laws of the State of Tennessee. Saint Thomas Neurosurgical's principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee, 37205. Saint Thomas Neurosurgical's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

21. Defendant Howell Allen Clinic A Professional Corporation, ("Howell Allen Clinic") is a Tennessee professional corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Howell Allen Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee, 37203.

22. Defendant Saint Thomas West Hospital is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the Saint Thomas West Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas West Hospital was formerly known as St. Thomas

Hospital. Saint Thomas West Hospital's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205. Hereinafter, Saint Thomas West Hospital shall be referred to as "St. Thomas Hospital."

23. At all times while providing treatment to Plaintiff at Saint Thomas Neurosurgical, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of St. Thomas Hospital and were acting within the course and scope of their employment, agency, or apparent agency with St. Thomas Hospital.

24. Pursuant to the doctrine of *respondeat superior*, St. Thomas Hospital is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while treating Plaintiff, as alleged below in the context of a strict products liability claim.

25. Defendant Saint Thomas Network is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the St. Thomas Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee, 37205.

26. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services.

27. Saint Thomas Network is a successor of Saint Thomas Health Services.

28. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

29. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

30. Defendant Saint Thomas Health is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas Health's registered agent for service of process is E. Berry Holt III, Suite 800,102 Woodmont Boulevard, Nashville, Tennessee, 37205.

31. Defendant Saint Thomas Health was formerly known as Saint Thomas Health Services.

32. Saint Thomas Health is a successor of Saint Thomas Health Services.

33. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

34. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.

35. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas."

36. At the time of the events described herein, Defendants Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.

37. The individuals and entities described in paragraphs 9-22 are sometimes collectively referred to as the "NECC Related Defendants."

38. The individuals and entities described in paragraphs 20-34 are sometimes collectively referred to as the "Tennessee Defendants."

JURISDICTION AND VENUE

39. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under title 11.

40. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

41. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

42. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies.

43. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

44. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: In re: *New England Compounding Pharmacy, Inc. Products Liability Litigation*, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

45. The Bankruptcy Court for the District of Massachusetts has not yet established a deadline for the filing of claims against NECC's bankruptcy estate in *In re: New England Compounding Pharmacy, Inc.*

46. By letter dated October 16, 2012, Saint Thomas Neurosurgical provided NECC with written notice of its intent to assert claims for breach of warranty and other remedies against NECC. In addition, Saint Thomas Neurosurgical and Howell Allen Clinic have actively represented themselves to the Bankruptcy Court for the District of Massachusetts as creditors of NECC who have a stake in NECC's bankruptcy proceeding as a result of Plaintiff's claims and the claims of those similarly situated. Saint Thomas Neurosurgical and Howell Allen Clinic objected to the Trustee's motion to establish a deadline for the filing of claims in Case no. 12:19882 HJB; they argued that the proposed deadline could prevent them from filing an accurate and comprehensive account of their contribution and indemnity claims against NECC. On July 24, 2013, during oral arguments on another motion filed in Case no. 12:19882 HJB, Saint Thomas Neurosurgical and Howell Allen Clinic characterized themselves to the Bankruptcy Court as creditors of NECC's bankruptcy estate possessed of indemnity and breach-of-warranty claims. In papers presented in response to that same motion, Saint Thomas Neurosurgical and Howell Allen Clinic insinuated that they intend to seek relief from the automatic stay for the purpose of pursuing indemnity claims against NECC.

47. Whatever contribution, indemnity, and breach-of-warranty claims Saint Thomas Neurosurgical and Howell Allen Clinic have against NECC are predicated on the contaminated methylprednisolone acetate purchased from NECC.

48. Upon information and belief, all of the Tennessee Defendants presently intend to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims

against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, all of the Tennessee Defendants presently intend to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

49. By Order dated May 31, 2013, Judge Saylor ruled that the New England Compounding Pharmacy, Inc., Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 11–21.

50. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

51. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing, and/or selling or administering, either directly or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

52. Defendants are subject to the jurisdiction of this Court in that they e transacted business within the State of Massachusetts, and acting individually and/or through their agents and employees have committed tortious actions and omissions in said state that have proximately caused the injuries that are the subject of this lawsuit.

53. The NECC Related Defendants described in the above paragraphs are further subject to the jurisdiction of this Court as a result of contracting to buy the stated products from the state of Massachusetts, by conducting or soliciting business in such state, by engaging in a persistent course of conduct, and by deriving substantial revenue from goods used or consumed or services prepared in such state.

STATEMENT OF FACTS

I. RELEVANT BACKGROUND

54. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

55. NECC was a compounding pharmacy that compounded, distributed, and/or sold drugs to purchasers throughout the United States.

56. Upon information and belief, NECC was a privately held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

57. Ameridose, GDC, MSM, and MSMSW were affiliates of NECC at all relevant times.

58. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC.

59. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

60. At least until October 2012, Glenn Chinn was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

61. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

62. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

63. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership — currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

64. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

65. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM. and/or MSMSW would perform services for NECC at the direction of NECC's principals.

66. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that

same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

67. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

68. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

69. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

70. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

71. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

II. CLAIMS AGAINST THE NECC-RELATED DEFENDANTS

72. NECC has a history well-known to the medical and pharmacy community of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012, Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of

compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

73. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC knew or should have known of these findings. NECC, Barry 'Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found.

74. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW, and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and Ameridose, MSM, and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

75. On September 26, 2012, in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab on Waverly Street in Framingham, Massachusetts.

76. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.

77. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.

78. Eighty-three out of three hundred twenty-one observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

79. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored

and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "non-complaints" and taking no action to address them.

80. The CDC determined that three lots of MPA produced by NECC between May 21 and September 26, 2012, were contaminated with potentially deadly pathogens.

81. In late September 2012, NECC recalled the following lots of methylprednisolone acetate that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

82. NECC identified Saint Thomas Neurosurgical in Nashville, Tennessee, as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.

83. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

84. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist.

85. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated

that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner " 247 CMR 6.02(1).

86. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

87. From May through September 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

88. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

89. ARL's May 25, 2012, Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5m1 vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

90. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

91. On or about August 10, 2012, NECC caused one vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

92. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.

93. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

94. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

95. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

96. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

97. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

98. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

99. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

100. GDC maintained a high degree of control over the premises leased by NECC.

101. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.

102. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

III. NECC AND THE RISKS OF PHARMACY COMPOUNDING

103. The serious risks of pharmacy compounding were also the subject of considerable discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years in the pharmacy and medical community.

104. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

105. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during

unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

106. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

107. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

108. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
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> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

109. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination

of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

IV. THE FUNGAL MENINGITIS OUTBREAK

110. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

111. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of epidural steroid injections at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

112. Dr. Kainer told personnel at St. Thomas Hospital that an event of concern had occurred in a patient who received epidural steroid injections at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

113. On September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.

114. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies, and ordered new supplies from other distributors.

115. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

116. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness, or swelling at the injection site. Death may result from meningitis.

117. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

V. SAINT THOMAS NEUROSURGICAL'S PURCHASE OF MPA FROM NECC

118. During all relevant times, Dr. John Culclasure and Ms. Debra Schamberg, R.N., co-managed Saint Thomas Neurosurgical's day to day operations.

119. During all relevant times, Dr. Culclasure and Ms. Schamberg were directly involved in and responsible for Saint Thomas Neurosurgical's decision to purchase MPA from NECC.

120. Saint Thomas Neurosurgical its agents and employees, including Dr. Culclasure and Ms. Schamberg, knew or should have known of the dangers of using compounded drugs and specifically products compounded by NECC. These defendants failed to undertake any appropriate due diligence to ascertain the safety and quality of NECC's products.

121. The sole motivation for Saint Thomas Neurosurgical to purchase steroids in bulk from NECC was price.

122. Saint Thomas Neurosurgical made the decision to purchase MPA in bulk from NECC because it was the cheapest steroid.

123. The Saint Thomas Neurosurgical defendants did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC compounded steroids to their patients. The Saint Thomas Neurosurgical defendants placed their own profits over patient safety.

124. NECC was not authorized to compound and sell MPA in bulk to Saint Thomas Neurosurgical.

125. NECC was only allowed to fill individual prescriptions for individual patients written by appropriately licensed healthcare providers.

126. Saint Thomas Neurosurgical did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

127. Saint Thomas Neurosurgical could have purchased MPA for use in epidural steroid injections ("ESI") from a compounder other than NECC.

128. Saint Thomas Neurosurgical could have purchased MPA for use in ESI's from a traditional, FDA-regulated pharmaceutical manufacturer, e.g., Pfizer.

129. From 2000 to the present the medication formulary for Saint Thomas Neurosurgical lists those steroids acceptable for use at Saint Thomas Neurosurgical and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.

130. The Saint Thomas Neurosurgical formulary does not include generic methylprednisolone acetate ("MPA") or MPA from a compounding company as acceptable for use at Saint Thomas Neurosurgical.

131. The Saint Thomas Neurosurgical formulary does include and allow for the administration of methylprednisolone acetate manufactured by Pfizer under the name Depomedrol.

132. In late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals.

133. Clint Pharmaceuticals represents that it has historically recommended that practitioners not use compounded steroids especially when FDA approved products are available. Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the price of $6.49 per 80mg vial.

134. In May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's facility director, Ms. Schamberg, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. Ms. Schamberg replied that if NECC could get the price under $6.50 per vial she would be willing to "talk" to NECC.

135. On June 9, 2011, Clint Pharmaceuticals increased the price to Saint Thomas Neurosurgical for MPA from $6.49 to $8.95 per vial, an increase of $2.46 per vial.

136. Saint Thomas Neurosurgical was not willing to pay $8.95 per vial of MPA from Clint Pharmaceuticals if it could be procured more cheaply from NECC.

137. On June 10, 2011, Ms. Schamberg on behalf of Saint Thomas Neurosurgical emailed an NECC sales representative indicating that if NECC would guarantee a price for MPA

of $6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC.

138. After NECC indicated its willingness to sell Saint Thomas Neurosurgical MPA for $6.50 per 1mL 80mg vial, Ms. Schamberg obtained approval from Dr. Culclasure to begin ordering from NECC.

139. Both Ms. Schamberg and Dr. Culclasure, as agents and/or employees of Saint Thomas Neurosurgical, approved the purchases of MPA from NECC.

140. Saint Thomas Neurosurgical placed its first order with NECC on or about June 10, 2011. That order consisted of 500 lmL 80 mg vials of MPA and 200 2mL 80 mg vials of MPA.

141. The June 2011 order did not contain any patient names despite the fact that the order form included a column for that information.

142. As evidenced by Dr. John Culclasure's name/signature on the June 2011 order form, Dr. Culclasure was aware of and approved the purchase of MPA from NECC.

143. NECC sent invoices to Saint Thomas Neurosurgical evidencing five separate purchases by Saint Thomas Neurosurgical of five-hundred 80 mg. vials of MPA as reflected in invoices dated June 6, 2012; June 26, 2012; July 25, 2012; August 13, 2012; and August 31, 2012.

144. NECC charged Saint Thomas Neurosurgical $6.50 for each 80 mg. vial of MPA.

145. In early to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed Saint Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy rules.

146. Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA. The NECC representative indicated that a list of previous patient names would suffice.

147. Dr. Culclasure and Ms. Schamberg acting on behalf of Saint Thomas Neurosurgical provided NECC with a list of previous patients' names (including Mickey Mouse) with their order(s) for MPA from NECC.

148. A list of patient names was submitted to NECC by Saint Thomas Neurosurgical showing the name "Mickey Mouse."

149. Defendant Saint Thomas Neurosurgical knew or should have known that sending a list of previous patient names to NECC including "Mickey Mouse" was inappropriate. Such conduct evidenced an effort by Saint Thomas Neurosurgical , through its agents and/or employees including Dr. Culclasure and Ms. Schamberg, to collude with NECC and was an effort to subvert the individual prescription rule of the Massachusetts Board of Pharmacy.

150. At the time of the relevant conduct, Tennessee law also imposed a patient safety rule that prohibited the sale and use of compounded medications except pursuant to a valid patient prescription. The conduct of NECC, aided and abetted by Saint Thomas Neurosurgical, would have also violated this patient safety rule. Saint Thomas Neurosurgical knew or should have known of this patient safety rule at the time it aided and abetted NECC in violating the applicable patient safety rules.

151. By sending the list of previous patient names to NECC, Defendant Saint Thomas Neurosurgical unlawfully conspired with NECC to violate a patient safety rule thereby resulting in harm to Plaintiffs and other patients who received NECC's MPA.

152. In September of 2012, Plaintiff received an epidural steroid injection at a Saint Thomas Neurosurgical facility. During that procedure a doctor injected MPA into Plaintiff's body.

153. Prior to being sold the injections, Plaintiff was never informed that she was being injected with medication compounded by NECC.

154. One or more of the injections into Plaintiff's body came from contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.

155. Plaintiff's injection of MPA caused her to be diagnosed with meningitis along with complications related to cerebral spinal fluid.

156. The MPA injected into Plaintiff's body came from one or more of the recalled contaminated lots.

157. As a direct and proximate result of the contaminated epidural steroid injections, Plaintiff contracted fungal meningitis, became very ill, and continues to suffer from the effects of fungal meningitis.

CAUSES OF ACTION

COUNT I
NEGLIGENCE
(Against NECC-Related Defendants)

158. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Plaintiffs to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiffs.

159. Specifically, but without limitation:

a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin owed Plaintiffs a duty to provide methylprednisolone acetate that was safe and free of contamination.

b. ARL owed Plaintiffs a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

160. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing, and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer, and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

161. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.

162. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiffs by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

163. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin was a proximate cause of Plaintiffs' injuries.

164. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into Plaintiff in 2012.

COUNT II
NEGLIGENCE PER SE
(Against all NECC-Related Defendants except ARL)

165. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin owed Plaintiffs a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

166. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiffs by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

167. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

168. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin were a proximate cause of Plaintiffs' injuries.

COUNT III
NEGLIGENT SUPERVISION
(Against NECC-Related Defendants)

169. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin had an

obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market, and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

170. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.

b. Defendants also failed to monitor and supervise the testing of the compounded medications.

c. The Defendants were negligent in hiring, training, and supervising their employees.

171. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

172. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff.

173. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin were a proximate cause of Plaintiffs' injuries.

COUNT IV
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

174. At all relevant times, Barry Cadden, Gregory Conigliaro, and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

175. Barry Cadden, Gregory Conigliaro, and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts, in a condition that was free from contamination.

176. Barry Cadden, Gregory Conigliaro, and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

177. The failure by Barry Cadden, Gregory Conigliaro, and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts, was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

178. Barry Cadden, Gregory Conigliaro, and GDC unreasonably and significantly interfered with the public health and the public safety.

179. Barry Cadden, Gregory Conigliaro, and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

180. The public nuisance created by Barry Cadden, Gregory Conigliaro, and GDC was a proximate cause of Plaintiffs' injuries.

181. The public nuisance created by Barry Cadden, Gregory Conigliaro, and GDC has caused Plaintiff special injury in that Plaintiff has sustained injuries to her personal health.

COUNT V
PRODUCT LIABILITY CLAIMS
(Against Saint Thomas Neurosurgical, Howell Allen Clinic and the Tennessee Defendants)

182. The MPA injected into Plaintiff's lumbar spine in 2012 was compounded by NECC.

183. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, *In re: New England Compounding Pharmacy, Inc.*, case no. 12-19882-HJB.

184. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

185. Plaintiffs could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

186. Plaintiffs' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

187. NECC has ceased operations.

188. NECC is unable to pay its debts as they fall due.

189. NECC is unable to pay its debts in the ordinary course of its business.

190. NECC's liabilities exceed its assets.

191. NECC is insolvent.

192. On July 24, 2013, The United States Bankruptcy Court for the District of Massachusetts in *In re: New England Compounding Pharmacy, Inc.*, Case no. 12-19882-HJB, ordered that with respect to certain claims, including those asserted by Plaintiffs in this lawsuit, NECC is presently insolvent and has been insolvent at all times since the petition date.

193. Saint Thomas Neurosurgical procured from NECC the MPA injected into Plaintiff.

194. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Saint Thomas Neurosurgical and Howell Allen Clinic injected it into Plaintiff in 2012.

195. Saint Thomas Neurosurgical and Howell Allen Clinic charged Plaintiff for epidural steroid injections administered to Plaintiff.

196. Saint Thomas Neurosurgical and Howell Allen Clinic, jointly or in concert with the Tennessee Defendants acted as sellers or distributors of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Plaintiff.

197. Saint Thomas Neurosurgical and Howell Allen Clinic were engaged in the business of selling MPA compounded by NECC, jointly or in concert with the Tennessee Defendants.

198. Accordingly, the Tennessee Defendants, including Saint Thomas Neurosurgical and Howell Allen Clinic are "sellers" as defined by Tenn. Code Ann. § 29-28-102(7).

199. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiffs to prosecute product liability claims against Saint Thomas Neurosurgical, Howell Allen Clinic, as the seller of the MPA injected into Plaintiff because the compounder of the product, NECC, cannot be served with process in this state.

200. Tenn. Code Ann. § 29-28-106(5) authorizes Plaintiffs to prosecute product liability claims against Saint Thomas Neurosurgical and Howell Allen Clinic as the seller of the

MPA injected into Plaintiff because the compounder of the product, NECC, has been judicially declared insolvent.

201. The MPA that Saint Thomas Neurosurgical and Howell Allen Clinic injected into Plaintiff was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

202. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

203. The MPA sold and distributed by Saint Thomas Neurosurgical and Howell Allen Clinic, alone or as part of the Tennessee Defendants was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic, and the Tennessee Defendants breached their warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314, and 47-2-315, including their warranty of fitness for a particular purpose.

204. Saint Thomas Neurosurgical, Howell Allen Clinic and the Tennessee Defendants are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Plaintiff.

DAMAGES

205. As a direct and proximate result of the Defendants' wrongful conduct as described above, Plaintiff has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.

206. The long term effects of Plaintiff's illness are unknown.

207. Plaintiff has incurred and continue to incur medical and other expenses.

PUNITIVE DAMAGES

208. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

209. Plaintiffs seek a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that the caps on personal injury and punitive damages set forth in Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are an unconstitutional deprivation of the right to trial by jury set forth in Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate, and violate the provisions of Article XI, Section 16, of the Constitution of the State of Tennessee which absolutely precludes the Legislature from exercising any legislative power to remove or restrict the right of juries in civil cases to determine damages.

210. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiffs' non-economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

211. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiffs' constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6, of the Constitution of the State of Tennessee, which

provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17, of the Tennessee Constitution, which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16, of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate."

212. Therefore, Plaintiffs request a declaration that the statutory caps are unconstitutional, void *ab initio*, and of no force and effect.

213. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiffs are challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann § 29-39-104.

PLAINTIFFS' COMPLIANCE WITH TENN. CODE ANN. §§ 29-26-121 AND 29-26-122

214. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act (the "TMMA"), T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, on September 6, 2013, but sixty days have not yet passed since service of those letters. Plaintiff files this action to preserve a products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

215. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the

Tennessee Medical Malpractice Act (the "TMMA"), T.C.A. § 29-26-101, *et. seq*. Plaintiff has served notice letters as required by the TMMA, but sixty days have not yet passed since service of those letters. Plaintiff files this action to preserve a products liability action, and will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

1. A judgment to each plaintiff for compensatory damages in excess of $75,000;

2. A judgment for punitive damages in an amount to be determined by the trier of fact;

3. A jury be empaneled to try this cause;

4. For costs of this cause; and

5. For such further relief as the Court may deem just and proper.

Dated: October 3, 2013

Respectfully submitted,

/s/ Mark Zamora
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Admitted via Pro Hac Motion in the MDL
1:13-md-02419-FDS